MAR - 4 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi
Date of Application: 09/25/2013

2.0 Device information

Trade name: Andon Blood Pressure Cuff
Device name: Blood Pressure Cuff
Classification name: Blood pressure Cuff

3.0 Classification

Production code: DXQ
Regulation number: 870.1120
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

1	Manufacturer:	APK Technology Co, Ltd
	Device:	Blood Pressure Cuff
	510(k) number:	K102825

5.0 Intended use

Blood Pressure Cuffs are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to complete the measurement of blood parameters on adults.

6.0 Device description

The proposed device, Blood Pressure Cuff, is a rectangle soft inelastic sleeve reusable with a bladder. There is a single-tube connected to the bladder and the Non Invasive Blood Pressure Monitor for inflating and deflating. The device should connected to a Non Invasive Blood Pressure Monitor to complete the function. There is various sizes for different arm range as follows:

Model	Arm range
KD-525-P31	20cm-34cm
KD-525-P32	30cm-44cm
KD-525-P33	40cm-48cm
KD-525-P34	15cm-24cm
KD-5917-P42	22cm-42cm

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Function	Identical

8.0 Discussion of non-clinical and clinical test performed

Non-clinical Tests have been done as follows:

a. Safety and performance characteristics of the test according to IEC 80601-2-30
b. Biocompatibility test has been performed according to ISO 10993-5 and ISO 10993-10
None of the test demonstrates that the Blood Pressure Cuffs bring new questions of safety and effectiveness.

Clinical Test Concerning the Compliance of ANSI/AAMI SP10

Clinical test has been done in accordance with IEC 80601-2-30-Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, and the test result shows, the device met all applicable requirements of the standard.

9.0 Performance summary

The new cuffs conform to the following standards:

- IEC 80601-2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk manangement process
- ISO 10993-5: Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytoto xicity.
- ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

10.0 Comparison to the predicate device and the conclusion

Compared to the predicate device, the new cuffs are very similar in the intended use, the design principle, the material, the performance and the applicable standards.
However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.
So we claims the proposed cuffs to be Substantially Equivalent (SE) to the predicate devices Blood Pressure Cuff(K102825).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 4, 2014

Andon Health Co., Ltd
Liu Yi
No. 3 Jinping Street, Ya An Road,
Nankai District
Tianjin, 300190 CN

Re: K133117
Trade/Device Name: Andon Blood Pressure Cuff (Model: KD-525-P31, KD-525-P32, KD-525-P33, KD-525-P34, KD-5917-P42)
Regulation Number: 21 CFR 870.1120
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXQ
Dated: January 2, 2014
Received: January 6, 2014

Dear Liu Yi,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems

(QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K133117

Device name: Andon Blood Pressure Cuff (Model: KD-525-P31, KD-525-P32, KD-525-P33, KD-525-P34, KD-5917-P42)

Indications for use:

Blood Pressure Cuffs are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to complete the measurement of blood parameters on adults.

Prescription use _____ AND/OR Over-The-Counter Use YES
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.03.04 14:41:16 -05'00'

for Bram Zuckerman